

Message Text

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TAGS: TBIO, OTRA (WAYNE, CHARLES A.), JA

SUBJ: MARUYAMA VACCINE: VISIT OF FDA INSPECTOR

REF: STATE 131573

OES/SCI/BMP FOR DR. M.S. BEAUBIEN

DEPT PASS TO NATIONAL CANCER INSTITUTE FOR DR. WILLIAM TERRY

FROM CHARLES A. WAYNE TO FDA FOR JOSEPH P. O'MALLEY, M.D. HFB-42,
AND RICHARD MCDERMAID, HFO-120

BEGIN REPORT:

1. INTERVIEWED DRS. CHISATO MARUYAMA AND KEISHIRO FUJITA, CO-WORKER,
AT NIPPON MEDICAL SCHOOL, TOKYO, JAPAN, FOR TWO AND HALF HOURS ON
JUNE 10, 1975. ALSO PRESENT FOR PART OF THE TIME WAS ROBERT W. WHY-

MANT, FAR EAST CORRESPONDENT, MANCHESTER GUARDIAN, MANCHESTER,
ENGLAND, WHO WAS INTRODUCED BY DR. FUJITA, THE SPOKESMAN FOR DR.
MARUYAMA, AS HIS INTERPRETER. MR. WHYMANT WROTE AN ARTICLE ON
MARUYAMA VACCINE IN THE GUARDIAN OCTOBER 21, 1974. HE HARDLY SPOKE
DURING THE INTERVIEW.

2. DR. MARUYAMA IS CURRENTLY NEGOTIATING WITH A MAJOR JAPANESE
PHARMACEUTICAL COMPANY TO LICENSE THEM TO PRODUCE THE VACCINE ON
INDUSTRIAL BASIS FROM BEGINNING TO END INCLUDING STRAIN OF TUBERCLE
BACILLUS. LATER, THIS PHARMACEUTICAL COMPANY, WHOSE IDENTITY DR.
FUJITA DECLINED TO REVEAL, MAY RELICENSE COMPANIES IN OTHER COUNT-
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RIES ON SAME BASIS, I.E., INDUSTRIAL PRODUCTION OF MARUYAMA VACCINE.

DR. FUJITA DESCRIBED THE CURRENT NEGOTIATIONS FOR LICENSING THE ENTIRE PROCESS INCLUDING THE MARUYAMA STRAIN OF TUBERCLE BACILLUS AS DELICATE. FOLLOWING LICENSING, THE TARGET DATE FOR WHICH IS UNCERTAIN, THE PHARMACEUTICAL COMPANY WILL PROBABLY INCREASE THE PRICE OF MARUYAMA VACCINE TO THE SAME LEVEL BEING CHARGED FOR OTHER CANCER VACCINES IN JAPAN. THE NEGOTIATIONS HINGE ON PROPER COMPENSATION TO DR. MARUYAMA.

3. THE INITIAL STEPS OF THE PROCESS WHICH INCLUDE CULTURING, EXTRACTION AND ISOLATION ARE CLAIMED TO BE DONE BY DR. MARUYAMA AT NIPPON MEDICAL SCHOOL. SINCE 1965, THE ISOLATED EXTRACT HAS BEEN PROCESSED TO THE FINISHED 1CC AMPULS BY A PHARMACEUTICAL COMPANY IN JAPAN WHOSE IDENTITY DR. FUJITA DECLINED TO REVEAL. THEREFORE, I WAS UNABLE TO INSPECT THAT PART OF THE OPERATION. DR. MARUYAMA REFUSED TO SHOW ME HIS MANUFACTURING RECORDS AND THE SITE WHERE HE CLAIMS HE PERFORMS HIS PART OF THE OPERATION. HE SAID HE WILL SHOW ME THE RECORDS AFTER HE HAS PUT THEM IN ORDER ON MY NEXT VISIT ON JULY 17, 1975. DRS. MARUYAMA AND FUJITA ARE AVAILABLE ONLY BETWEEN 3 AND 5 PM ON TUESDAYS AND THURSDAYS, BECAUSE DR. FUJITA, AN ENERGETIC PERSON IN HIS EARLY FORTIES, IS A BUSY GYNECOLOGIST WHO SPECIALIZES IN GYNECOLOGICAL OPERATIONS.

4. DR. FUJITA IS NOT TOO CONVERSANT WITH THE PROCESS. HE HAD TO CONSULT DR. MARUYAMA SEVERAL TIMES FOR ANSWERS TO MY QUESTIONS. FOR PRODUCTION AND TESTING INFORMATION, DR. FUJITA TELEPHONED THE PHARMACEUTICAL COMPANY WHICH PROCESSES THE ISOLATED EXTRACT TO THE FINISHED AMPULS AND I SPOKE TO A MR. SUZUKI AT THE UNIDENTIFIED FIRM. LATER, DR. FUJITA GAVE ME MR. SUZUKI'S TELEPHONE NUMBER IN ORDER THAT I OBTAIN ADDITIONAL PRODUCTION INFORMATION WHICH I REQUESTED CONCERNING CONTROL OF THE CONSISTENCY OF THE PRODUCTION PROCESS FROM LOT TO LOT WHICH ARE NOT TESTED FOR POTENCY BECAUSE NO PRACTICAL METHOD EXISTS.

5. DRS. MARUYAMA AND FUJITA CLAIM THEY WERE GIVEN INSUFFICIENT NOTICE OF THE INSPECTION. THEY REQUESTED A LIST OF QUESTIONS TO WHICH THEY SAID THEY WOULD RESPOND. I WILL FURNISH THEM THE LIST OF 13 QUESTIONS POSED BY DR. O'MALLEY BUT NOT THE LIST OF INVESTIGATORS.

6. I ENCOUNTERED RELUCTANCE ON THE PART OF DR. MARUYAMA WHO TOLD ME IN ENGLISH THAT HE SPEAKS AND UNDERSTANDS VERY LITTLE ENGLISH.

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DR. FUJITA SPEAKS ENGLISH FLUENTLY AND UNDERSTANDS IT. THE EMBASSY FURNISHED ME AN INTERPRETER WHO WAS PRESENT DURING THE INTERVIEW.

7 AMPULS ARE CLAIMED TO BE TESTED FOR PYROGENS, VISUAL FOREIGN MATTER AND STERILITY BY THE COMPANY WHICH PRODUCES THE AMPULS. THE STERILITY IS DONE ON TEN AMPULS IN FLUID THIOGLYCOLLATE, GLUCOSE-PEPTONE FOR CANDIDA AND CORN STARCH. THE BULK VACCINE IS NOT TESTED BEFORE FILLING IN AMPULS. THE AMPULS ARE NOT TESTED FOR POTENCY OR

SAFETY. DR. FUJITA SAID SAFETY TESTING IS NOT NECESSARY, BASED ON
PREVIOUS EXPERIENCE, WHICH MEANS DR. MARUYAMA'S WORK AND THE EXTENT
TO WHICH THE PRODUCT HAS BEEN USED ON PATIENTS WITHOUT ILL EFFECT.
VERY LITTLE OTHER INFORMATION WAS OBTAINED. I HOPE TO OBTAIN MORE
ON MY NEXT VISIT. I HAVE A 2PM APPOINTMENT ON JULY 17, 1975. END
REPORT.
HODGSON

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